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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,907	11/24/2003	Mel Rich	33345/US/4	5293

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EXAMINER

SPEAR, JAMES M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary

Application No.

10/720,907

Applicant(s)

RICH ET AL.

Examiner

James M. Spear

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. The amendment filed 20 October 2004 has been entered.
2. After further review and consideration the following new grounds of rejection are deemed necessary.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for “a method of treating cell oxidative damage in humans” or “a method of protecting against cell oxidative damage in humans”, does not reasonably provide enablement for “a method to protect cells in a lipid bilayer membrane”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. See page 3, line 29 through page 4, line 31.
5. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988). These factors include, but are not limited to.

The breadth of the claims;

The nature of the invention;

The state of the prior art;

The level of one of ordinary skill;

The level of predictability in the art;

The amount of direction provided by the inventor;

The existence of working examples; and

The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

When the above factors are weighed, it is the position of this office that the disclosure fails to meet the enablement requirement for the following reasons:

The breadth of the claims: The claims are very broad. Claim 1 is directed to a method to protect cells in a lipid bilayer membrane, however the specification at most discloses a relationship with cells and oxidation as cited above, page 4, lines 15-21. No mention of lipid bilayer is evident. There is no evidence to describe what the limitations of a lipid bilayer membrane are. Animal, mammal, human etc. The specification appears

limited to treating humans. Claim 1 broadly encompasses anything having cells comprised of a lipid bilayer membrane.

The nature of the invention: Because the claims are very broad the actual nature of the invention is not clear. A vitamin E formulation is disclosed. While claim 1 is limited to an asserted effect on a lipid bilayer, the particular association between the bilayer and Vitamin E is not supported in the specification. It is also noted that claims 2 and 3 are limited to a lipid layer. The specification does not distinguish or support these apparent distinct elements.

The state of the prior art: Antioxidants such as Vitamin E are well known in the art as indicated in applicants' disclosure.

The level of one of ordinary skill in the art: The level of one of ordinary skill in the art is high. However it is believed that one skilled in the art would be more concerned and familiar with overall effects on living beings experiencing oxidative reactions from a pharmaceutical or cosmetic point of view because a formulation comprised of different Vitamin E components is utilized.

The level of predictability in the art: There would be a general lack of predictability in the art. It is believed that one skilled in the art would have

difficulty predicting the effect on a distinct lipid bilayer membrane because of the distinct differences in the cells associated with such membranes. Furthermore the formulation comprised of multiple elements in various ratios and proportions would not necessarily elicit the same effect when exposed to the same or similar membranes. Numerous variables lead to unpredictability in this art.

The amount of direction provided by the inventor: The inventor has provided broad general statements supporting evidence of an antioxidant efficacy for a Vitamin E formulation, however no direction in protecting or treating lipid bilayer membranes. Page 5, line 4 through page 6, line 3.

The existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure: An ingestible formulation is disclosed, however an assertion of an effect on a cell membrane lipid bilayer is unsupported. Page 10, lines 2-33. No guidance is presented to determine actual efficacy of the claimed invention. While reference to an ORAC assay is made there is no correlation between such an assay and actual inventive results as claimed. Page 7, line 19 through page 8, line 18.

When the above factors are weighed, it is the position of this office that one skilled in the art could not practice the invention without undue experimentation.

Claims 1-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

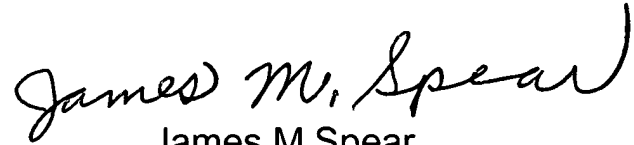
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

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access to the Private PAIR system, contact the Electronic Business Center
(EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "James M. Spear". The signature is written in a cursive, flowing style.

James M Spear
Primary Examiner
Art Unit 1615

March 3, 2005